

Health System Initiative to Reduce Unnecessary Daily X-Ray Image Guidance During Palliative Radiation Treatment

Final Study Protocol
January 25, 2017

ClinicalTrials.gov NCT Number: NCT03110692

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1. Abstract

The goal of this study is to reduce preference sensitive, unnecessary daily imaging during radiation treatment in which a pre-planned quality improvement default option for radiation treatment prescriptions will be introduced throughout the network of Penn Radiation Oncology. This study is a pragmatic stepped wedge trial with two comparison groups: (1) a usual practice group (control group) and (2) a default radiation treatment prescription group (intervention group), in which the usual practice group will subsequently rollover from control to intervention so that all sites and physicians in the practice network of Penn Radiation Oncology are exposed to intervention.

2. Overall objectives

The purpose of this study is to reduce preference sensitive, unnecessary daily imaging during radiation treatment with the implementations of a quality improvement initiative within 5 sites of Penn Radiation Oncology. We aim to leverage the introduction of a default prescription option to reduce the use of daily imaging in palliative intent cases where it has limited clinical benefit and adds to cost burden. Our objective is to encourage more patient-centric clinical practice.

3. Aims

3.1 Primary outcome

The primary objective of this study is to reduce unnecessary daily imaging during palliative radiation treatments.

4. Background

4.1 Value-based cancer care. With exponentially rising healthcare costs, providers practice medicine in an increasingly value conscious environment.¹⁻⁵ Physicians are encouraged to reduce low-value care by eliminating unnecessary tests and procedures, thus, reducing healthcare costs at large. However, methods to optimally promote high value care are still under evaluation.

Radiation oncology, in specific, has come under scrutiny for expensive treatments and rising costs particularly with the advent of newer treatment technologies over the past 15 years.⁵⁻⁷ We aim to reduce low value care in a multi-site radiation oncology clinical practice.

4.2 Image-guided radiotherapy. Image-guided radiation therapy (IGRT) is a tool used in radiotherapy to ensure reproducible patient positioning during treatment. The two main technologies used to perform IGRT are kilovoltage x-ray images (KV), which are x-ray images to check patient alignment, and conebeam computed tomography (CBCT), which is a CT scan (also 'x-ray' based) done on the radiation treatment table. Regardless of whether IGRT is used, all patients have daily clinical positioning using immobilization devices and a calibrated treatment table with 3-dimensional lasers aligned to small tattoos placed on the body at the time of treatment planning.

The role of IGRT is evolving in the field of radiation oncology. While evidence for its clinical utility is uncertain or even limited in certain clinical situations,^{8,9} IGRT is used extensively amongst radiation oncologists and its use is projected to increase further.¹⁰ However, daily imaging beyond clinical positioning adds significant additional radiation exposure and increases the total time on the treatment table for patients who are often in pain or have limited mobility.

Given the limited evidence and lack of clarity regarding ideal use of IGRT, and the fact that all patients receive daily clinical positioning, insurance companies are increasingly denying the charges associated with such procedures. Furthermore, daily IGRT also places a considerable strain on clinic resources and efficiency.¹¹

Overuse of IGRT is particularly apparent during palliative radiation treatments. Our department has demonstrated that for the palliative treatment of brain metastases standard, clinical immobilization and setup techniques without the use of daily IGRT are sufficient for treatment in routine cases.⁸ Moreover, evidence-based guidelines clearly state that “IGRT generally is not medically necessary in the palliative setting.”¹² Yet despite uncertain clinical need and decreasing reimbursements, physicians often reflexively order daily imaging for treatment.

4.3. Preliminary data. At our institution, across the University of Pennsylvania Health System (UPHS) Radiation Oncology network, 79% of palliative intent radiation courses over the past year (August 2015 – August 2016) utilized daily x-ray image guidance as part of the treatment paradigm. As shown in Table 1, despite clinical guidelines recommending against the use of daily IGRT in palliative cases, 83% of bone metastases, 82% of soft tissue metastases, and 57% of palliative brain/ CNS cases employed daily IGRT during the associated radiation treatment course.

Table 1: Use of Daily IGRT in Palliative Cases at UPHS by Treatment Indication

Palliative Type	Total N	% Courses w Daily IGRT
Bone	459	83.4%
Brain/ CNS	133	57.1%
Soft Tissue	216	82.4%
Unknown	2	50.0%
SBRT	21	100.0%

*Daily IGRT defined as at least 80% (i.e., 4 of 5 days, on average) of treated fractions in a treatment course have IGRT

**SBRT: Stereotactic Body Radiation Therapy

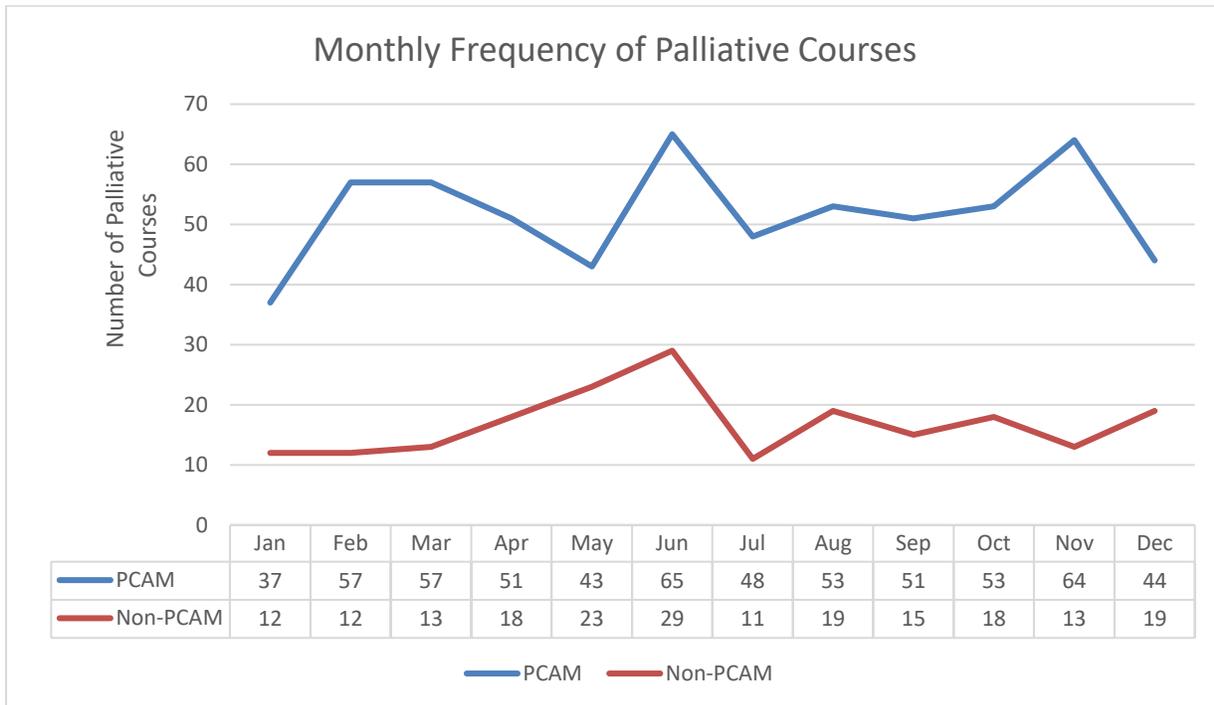
As shown in Table 2, the total number of palliative courses and associated daily IGRT varies across our main site and satellites. Our main site, the Perelman Center for Advanced Medicine (PCAM), has the highest volume of cases overall, and, hence, the highest number of palliative courses. All sites across the UPHS radiation oncology network, however, demonstrate high levels of daily IGRT usage in palliative courses. Over the past year, the number of palliative courses treated at each department was roughly stable over time as shown in Table 3, other than a slight rise in the number of cases treated during the month of June.

Table 2: Use of Daily IGRT in Palliative Cases by UPHS Radiation Oncology Department Location

Location	Total N	% Courses w Daily IGRT
PCAM	623	81.4%
PAH	56	58.9%
CHH	39	79.5%
DH	55	76.4%
VF	52	80.8%
Unknown	6	66.7%
Grand Total	831	79.3%

**PCAM: Perelman Center for Advanced Medicine; PAH: Pennsylvania Hospital; CHH: Chestnut Hill Hospital; DH: Doylestown Hospital; VF: Valley Forge

Table 3: Monthly Frequency of Palliative Courses



*PCAM: Perelman Center for Advanced Medicine

**Non-PCAM consists of satellites at Pennsylvania Hospital, Chestnut Hill Hospital, Doylestown Hospital, and Valley Forge

4.4. Default options. We have described how default options can be an effective means of reducing low-value services in cancer care and other healthcare settings.¹³⁻¹⁵ Defaults may promote high-value care by introducing a treatment standard indicative of evidence-based guidelines or institutional recommendations.¹⁵ For instance, in our own health system, a change in default drug prescription options in the electronic health record (EHR) has been successfully leveraged to reduce the prescription of low-value, brand name medications.¹³ *Default options*

*provide a unique means of influencing decision-making while preserving physician choice; importantly, default prescriptions may be altered by treating physicians to best serve the needs of their patients.*¹⁵⁻¹⁷

At Penn Radiation Oncology, default prescriptions for radiation are the norm. These defaults exist currently in non-palliative settings and involve template prescription order sets that contain default settings. These default prescription templates improve clinic workflow and standardize clinical care. Importantly, as always with default prescription options, physician choice is preserved.

In the initiative proposed herein, we aim to introduce a default prescription template in the palliative setting. This effort is part of the department's overarching quality improvement initiative to standardize treatment approaches. With defaults, the physician has the option to alter default order sets to fit their clinical decisions. This is true for all other default prescription order sets already in use in our clinic. In other words, default options for curative, non-palliative treatments are currently standard of care in our clinic as a means of improving efficiency and standardizing care across our network, and we plan to rollout default options for palliative treatments in order to reduce unnecessary daily image guided radiation.

4.5 Quality Improvement Initiatives in the Radiation Oncology Department: The Penn Medicine Department of Radiation Oncology (also called Penn Radiation Oncology) has a long history of excellence in quality improvement and safety initiatives. QI initiatives are typically implemented first at either PCAM or non-PCAM sites and then rolled out to the entire clinical practice. Continuous quality improvement is conducted through monitoring and comparisons of physician and site rates of care delivery, depending on the focus of the QI initiative, and iterative changes to improve initiatives are then implemented over time. In this study, we leverage the existing departmental processes for QI implementation, and we will choose the first site of intervention implementation by coin flip rather than arbitrarily as has been done in the past.

Our study is sponsored and approved by our health systems partners including the Office of the Chair of Radiation Oncology and the Penn Medicine Nudge Unit.

5. Study design

5.1 Design

In this study, we propose to leverage a pre-planned departmental initiative of default prescriptions to reduce unnecessary daily x-ray imaging in palliative radiation treatments.

This study follows a pragmatic stepped wedge design with two comparison groups: (1) a usual practice group (control group) and (2) a default radiation treatment prescription group (intervention group), in which the usual practice group will subsequently rollover from control to intervention. One group is comprised of physicians who practice at the Perelman Center for Advanced Medicine (PCAM). Another group is comprised of non-PCAM physicians at our network satellites (Pennsylvania Hospital, Chestnut Hill Hospital, Doylestown Hospital, and Valley Forge). As is standard practice for implementation of QI initiatives in our department, we will implement the intervention at one network site prior to implementing the intervention at all

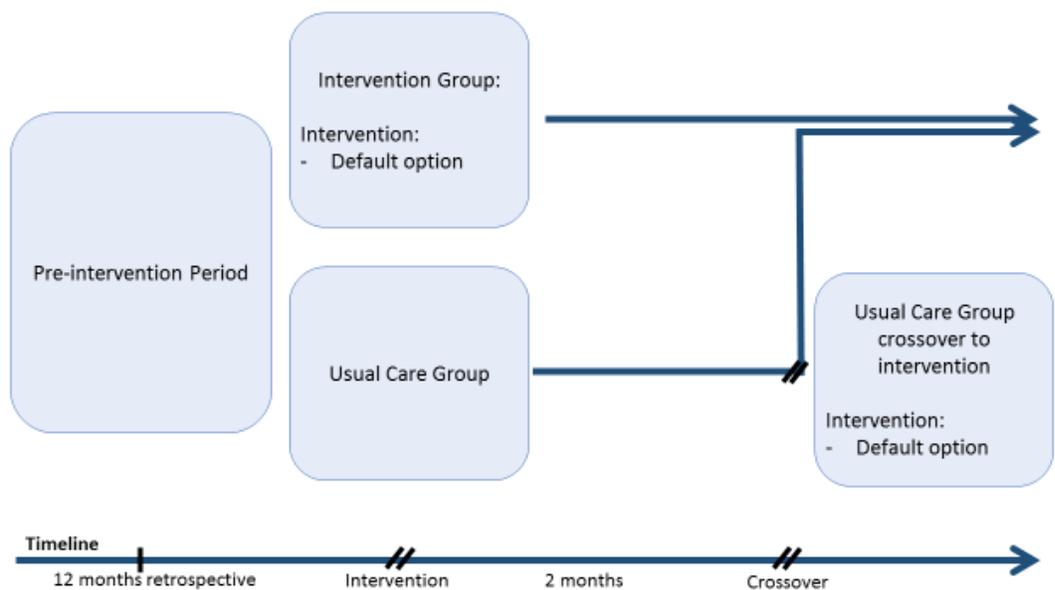
sites. These groups will be assigned to the intervention or usual care at the start of the study by coin flip. Subsequently, the usual practice group will rollover into the default intervention.

Intervention. The default intervention will be started in February 2017. It will be comprised of default prescription order sets that do not include daily imaging for brain/ CNS, bone, and soft tissue metastases (See Figure 1). The defaults will be immediately preceded by a department wide session with intervention group physicians and therapy staff announcing the initiation of the intervention. Thus, as is usual practice in the department, physicians and department staff will be aware and educated on the QI initiative at the time of implementation. Default prescription order sets will be created in Aria (the radiation oncology electronic health record) for specific palliative treatment indications, namely brain/CNS, bone, soft tissue, and other palliative cases.

Figure 1: Example of Default IGRT Prescription for Palliative Cases

IGRT-LOCALIZATION INSTRUCTIONS:	
PRIMARY (Match for Treatment)	SECONDARY (EVAL)
Modality: None	Modality: None
Frequency: Other	Frequency: Other
Match Instructions: Set up with attention to immobilization, tattoo markers, and weekly MV portal films	Additional / Special Instructions:
Additional / Special Instructions: do not take KV-KV image	
Localization Instructions For CD Or Other If Different From Initial:	

Figure 2: Study Framework



*Coin flip to determine initial intervention vs. usual care group:

Group 1: PCAM Physicians

Group 2: Non-PCAM Physicians (Pennsylvania Hospital, Chestnut Hill Hospital, Doylestown Hospital, and Valley Forge)

The study will involve our entire physician network across the UPHS Radiation Oncology network, including both PCAM and regional network facilities (Pennsylvania Hospital, Chestnut Hill Hospital, Doylestown Hospital, and Valley Forge).

5.2 Study duration

The duration of the study will be 27 months, including the 12 retrospective pre-intervention study period, 1 month for the intervention, 2 months for the first post-intervention study period, 1 month for the control to cross over to the intervention, and 2 additional months for observation in which all physicians are exposed. Analysis of data and dissemination of results will occur in the 9 month period following the 2nd post-intervention period.

5.3 Target population

The study will include a total of ~29 subjects (UPHS radiation oncologists) and 5 sites across the UPHS network (Perelman Center for Advanced Medicine, Pennsylvania Hospital, Chestnut Hill Hospital, Doylestown Hospital, and Valley Forge) that treat about 800 palliative patients a year. The University of Pennsylvania Radiation Oncology network (both PCAM and satellites) will be the only site of this study.

5.4 Accrual

Radiation oncology physicians will be recruited from the University of Pennsylvania Health System.

5.5 Key inclusion criteria

- Radiation treatment courses with palliative intent
- Palliative treatment of bone, soft tissue, and intracranial metastases
- Photon radiation with 3D conformal therapy (3DCRT) only

5.6 Key exclusion criteria

- Use of intensity modulated radiation (IMRT) or stereotactic body radiation (SBRT) as radiation treatment modality
- Retreatment to same site
- Proton radiation

6. Subject recruitment

Not applicable. Subjects will include all UPHS radiation oncologists. As a result, no recruitment will be needed in this study.

7. Subject compensation

No compensation will be offered in this study.

8. Study procedures

8.1 Consent

A waiver of informed consent is requested. This is a departmental quality improvement initiative that will be implemented regardless of the study we propose. The study is to evaluate that quality improvement initiative. Without a waiver of the consent, the initiative would still be implemented by the health system, but the study would be infeasible. Additionally, consenting every patient and physician would make the study impossible to conduct. As mentioned, this initiative would occur with or without the study of it. Furthermore, if physician members of the usual care group were consented, they would know they were being studied and this could bias their behavior, which would make our findings difficult to interpret. Moreover, physicians are not being forced to change their prescription of image guidance in radiation. Instead, they are being reminded of evidence-based guidelines and offered a default option which can be altered. The physician would continue to prescribe radiation treatment and whichever imaging they believe is appropriate for the patient. The intervention is simply a default option for the physician and makes their care process easier to conduct.

8.2 Procedures

Data on use of daily imaging will be obtained from Aria. De-identified patient-level demographic and disease-specific data will also be obtained from EPIC, including patient age, race, gender, cancer diagnosis, and insurance provider. Billing information associated with the IGRT CPT codes used in the pre and post-intervention radiation courses will be obtained from our revenues department.

8.3 Coin-flip to select initial site (randomization)

Group 1 (PCAM physicians) and 2 (non-PCAM physicians) will be assigned to either the intervention or control group prior to study initiation by coin flip (rather than arbitrarily as has been done in past QI efforts). The control group will then rollover to the intervention arm after 2 months.

9. Analysis plan

The primary analysis will use a mixed effects logistic regression model, where the unit of analysis is an individual patient, the outcome is use of daily x-ray imaging and the explanatory variables are time (pre-intervention vs. post-intervention period), dummy variable for whether the intervention is received, group (PCAM vs. satellite providers) and physician random effects. The coefficient of interest is the coefficient of whether the intervention is received. The physician random effects account for the clustering by physician. The study is analyzed at the physician level (patients clustered within physicians) rather than the practices site level because there are only two practice sites. Of the two practice sites – PCAM vs. non-PCAM sites – one group will be assigned to the intervention for the entire intervention period by coin flip, and the other group of providers will be assigned to the control for the first two months of the intervention period and then the intervention for the remaining four periods of the intervention. Randomly assigning the order of practice sites exposed to the intervention helps to blunt selection bias. For this analysis, we have 89% power to detect an effect of the intervention that reduces the probability of daily imaging by 0.2 for each physician.

10. Investigators

Sonam Sharma, MD: Principal Investigator (PI), Chief Resident, Department of Radiation Oncology at the Perelman School of Medicine at the University of Pennsylvania

Justin Bekelman, MD: Co-investigator, Associate Professor of Radiation Oncology and Medical Ethics & Health Policy Faculty, Senior Fellow at the Leonard Davis Institute for Health Economics.

Mitesh Patel, MD, MBA, MS: Director, Penn Medicine Nudge Unit, Assistant Professor of Medicine and Health Care Management at the Perelman School of Medicine at the University of Pennsylvania

Greg Kurtzman, BA: Clinical Research Coordinator, Penn Medicine Nudge Unit at the Perelman School of Medicine at the University of Pennsylvania

Dylan Small: Professor, Department of Statistics, The Wharton School at the University of Pennsylvania

Joshua Jones, MD: Assistant Professor, Department of Radiation Oncology at the Perelman School of Medicine at the University of Pennsylvania

David Guttman, MD, MTR: Resident, Department of Radiation Oncology at the Perelman School of Medicine at the University of Pennsylvania

Peter Gabriel, MD MSE: Assistant Professor, Department of Radiation Oncology at the Perelman School of Medicine at the University of Pennsylvania

11. Human research protection

11.1 Data confidentiality

Data will be collected on HIPAA-secure UPHS computers and computer-based files will be password-protected and available only to study personnel. When possible, patient identifiers will be removed from data files. Any patient or physician level data obtained will be used only for research purposes. All members of the research team will complete HIPAA and CITI training to remain compliant with PHI protection. Only trained study staff will have access to the code that links the unique identifier to the subject's identity. Electronic data will be stored on secure, password-protected firewalled servers at UPHS.

11.2 Subject confidentiality

Data on physicians and patients will be obtained from EPIC. Any information that is obtained will be used for research purposes only. Information on patients will only be disclosed within the study team. All study staff will be reminded of the confidential nature of the data collected and contained in these databases.

11.3 Subject privacy

All efforts will be made by study staff to ensure subject privacy. Data will be evaluated in a de-identified manner whenever possible.

11.4 Data disclosure

Information on patients will only be disclosed within the study team.

11.5 Data safety and monitoring

The investigator will provide oversight for the study evaluation of this intervention. Physician practices will follow their standards of care to treat patients with palliative radiation. The study PI will be responsible for ensuring the ongoing quality and integrity of the research study.

11.6 Risk/benefit

11.6.1 Potential study risks

The potential risks from this study and the intervention are minimal. Patients will continue to receive the standard of care in terms of radiation treatment as per their physician provider. Subjects in the study (UPHS radiation oncologists) will have minimal risk of harm. Breach of data is a potential risk that will be addressed as described above with the use of HIPAA compliant, password-protected electronic files, and secure data servers at UPHS.

11.6.2 Potential study benefits

The direct benefits of this study to the study participants (UPHS radiation oncologists) are minimal. The intervention to change defaults will promote evidence-based decision making. It will also have the indirect benefit of reducing radiation exposure for patients by decreasing the number of unnecessary images taken for patient positioning during treatment. Additional indirect benefits may include reducing costs and improving efficiency in the clinic by decreasing the use of daily imaging and patient time on the treatment table.

11.6.3 Risk/benefit assessment

Given the minimal risks to study participants and patients with an intervention to promote high-value care while maintaining standard radiation treatments, the benefits of this study (reducing low-value care, decreasing costs, reducing patient radiation exposure, improving clinic efficiency) outweigh the potential, minimal risks associated with the intervention.

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